Health Canada Santé Canada

Your health and safety... our priority. *Votre santé et votre sécurité... notre priorité.*

Proposed Maximum Residue Limit PMRL2014-42

Fludioxonil

(publié aussi en français)

28 July 2014

This document is published by the Health Canada Pest Management Regulatory Agency. For further information, please contact:

Publications
Pest Management Regulatory Agency
Health Canada
2720 Riverside Drive
A.L. 6604-E2
Ottawa, Ontario K1A 0K9

Internet: pmra.publications@hc-sc.gc.ca
healthcanada.gc.ca/pmra
Facsimile: 613-736-3758
Information Service:
1-800-267-6315 or 613-736-3799
pmra.infoserv@hc-sc.gc.ca

Canada

ISSN: 1925-0835 (print)
1925-0843 (online)

Catalogue number: H113-24/2014-42E (print version)
H113-24/2014-42E-PDF (PDF version)

© Her Majesty the Queen in Right of Canada, represented by the Minister of Health Canada, 2014

All rights reserved. No part of this information (publication or product) may be reproduced or transmitted in any form or by any means, electronic, mechanical, photocopying, recording or otherwise, or stored in a retrieval system, without prior written permission of the Minister of Public Works and Government Services Canada, Ottawa, Ontario K1A 0S5.

Under the authority of the *Pest Control Products Act*, Health Canada's Pest Management Regulatory Agency (PMRA) has concluded that the addition of new uses on strawberries and carrots to the product label of SCHOLAR® 230SC Fungicide, containing technical grade fludioxonil, is acceptable. The specific uses approved in Canada are detailed on the label of SCHOLAR® 230SC Fungicide, Pest Control Products Act Registration Number 29528.

The evaluation of these fludioxonil applications indicated that the end-use product has merit and value and the human health and environmental risks associated with the new uses are acceptable. Details regarding the registration of strawberries can be found in the corresponding Evaluation Report available in the Pesticides and Pest Management section of Health Canada's website, under Public Registry, Pesticide Product Information Database.[1]

Before registering a pesticide for food use in Canada, the PMRA must determine the quantity of residues that are likely to remain in or on the food when the pesticide is used according to label directions and that such residues will not be a concern to human health. This quantity is then legally established as a maximum residue limit (MRL). An MRL applies to the identified raw agricultural food commodity as well as to any processed food product that contains it, except where separate MRLs are specified for the raw agricultural commodity and a processed product made from it.

Consultation on the proposed MRLs for fludioxonil are being conducted via this document (see Next Steps, the last section of this document). A summary of the field trial data used to support the proposed MRL on carrot roots can be found in Appendix I.

To comply with Canada's international trade obligations, consultation on the proposed MRLs is also being conducted internationally by notifying the World Trade Organization, as coordinated by the Standards Council of Canada.

The proposed MRLs, to replace or be added to MRLs already established for fludioxonil, are as follows.

[1] The relevant report can be accessed by selecting Applications/Minor Use/Historical and requesting the Evaluation Report found under Application Number 2013-1316.

Table 1 Proposed Maximum Residue Limits for Fludioxonil

Common Name	Residue Definition	MRL (ppm)[1]	Food Commodity
Fludioxonil	4-(2,2-difluoro-1,3-benzodioxol-4-yl)-1H-pyrrole-3-carbonitrile	7.0[2]	Carrot roots
		3.0[3]	Low growing berry subgroup (Crop Subgroup 13-07G)

1 ppm = parts per million

2 The MRL of 7.0 ppm is proposed to replace the currently established MRL of 0.75 ppm for residues of fludioxonil in/on carrot roots

3 TheMRL of 3.0 ppm is proposed to replace the currently established MRL of 2.0 ppm for residues of fludioxonil in/on lingonberries and strawberries. In addition, the currently established MRL of 2.0 ppm for ' blueberries' is proposed to be revised to 3.0 ppm for lowbush blueberries, and 2.0 ppm for highbush blueberries to reflect updated terminology currently used to establish MRLs in Canada.

MRLs are proposed for each commodity included in the listed crop groupings in accordance with the Residue Chemistry Crop Groups webpage in the Pesticides and Pest Management section of Health Canada's website.

MRLs established in Canada may be found using the Maximum Residue Limit Database on the Maximum Residue Limits for Pesticides webpage. The database allows users to search for established MRLs, regulated under the *Pest Control Products Act*, both for pesticides or for food commodities.

International Situation and Trade Implications

MRLs may vary from one country to another for a number of reasons, including differences in pesticide use patterns and the locations of the field crop trials used to generate residue chemistry data.

Table 2 compares MRLs proposed for fludioxonil in Canada with corresponding American tolerances and Codex MRLs[2]. American tolerances are listed in the Electronic Code of Federal Regulations, 40 CFR Part 180, by pesticide. A listing of established Codex MRLs is available on the Codex Alimentarius Pesticide Residues in Food website, by pesticide or commodity.

2 The Codex Alimentarius Commission is an international organization under the auspices of the United Nations that develops international food standards, including MRLs.

Table 2 Comparison of Canadian MRLs, American Tolerances and Codex MRLs (where different)

Food Commodity	Canadian MRL (ppm)	American Tolerance (ppm)	Codex MRL (ppm)
Carrot roots	7.0	0.75 (vegetable, root, except sugar beet, subgroup 1B)	0.7
Low growing berry subgroup (Crop Subgroup 13-07G)	3.0	3.0 (Berry, low growing, subgroup 13-07G,except cranberry)	3 (strawberries) 2 (blueberries)

Next Steps

The PMRA invites the public to submit written comments on the proposed MRLs for fludioxonil up to 75 days from the date of publication of this document. Please forward your comments to Publications (see the contact information on the cover page of this document). The PMRA will consider all comments received before making a final decision on the proposed MRLs. Comments received will be addressed in a separate document linked to this PMRL. The established MRLs will be legally in effect as of the date that it is entered into the Maximum Residue Limit Database.

Appendix I

Summary of Postharvest Trial Data Used to Support the Proposed MRL for Carrot Roots

Residue data from post-harvest trials conducted in Canada were submitted to support the domestic use of SCHOLAR® 230SC Fungicide on carrots. Fludioxonil was applied to carrots as either a post-harvest dip or a post-harvest drench application at the proposed label rate.

Maximum Residue Limit

The recommendation for the maximum residue limit (MRL) for fludioxonil in/on carrot roots was based upon the submitted field trial data, and the guidance provided in the OECD MRL Calculator. Table A1 summarizes the residue data used to calculate the proposed MRL for carrot roots.

Table A1. Summary of Field Trial Data Used to Support Maximum Residue Limit (MRL)

Commodity	Application Method/ Total Application Rate (g a.i./L)	Preharvest Interval (days)	Residues (ppm)	
			Min	Max
Carrots	Postharvest treatment, dip and drench/ 0.3	0	1.63	3.49

Following the review of all available data, an MRL of 7.0 ppm is recommended to cover residues of fludioxonil. Residues of fludioxonil in carrot roots at the proposed MRL will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.